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09/954,494	09/17/2001	James G. Castillo	3863.015	8042

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	17

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/954,494	Applicant(s) CASTILLO, JAMES G.
	Examiner Vickie Kim	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed July 09, 2003. Upon entering the amendment, the claims 5 and 7 are canceled and claim 15 is amended. Claim 16 is newly added.

2. The claims 1-4, 6, 8-16 are pending and presented for the examination.

Response to Amendment

3. The declaration under 37 CFR 1.132 filed July 09, 2003 is insufficient to overcome the rejection of claims 1-15(now claims 5 and 7 are canceled) based upon 102 rejection, anticipated by Inagi et al (US 6,429,228) as set forth in the last Office action because: In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence fails to prove unexpected result(improvement) of the present invention over the composition of Inagi et al reference. In 132 declaration, applicant choose the composition 1(table 1 at columns 5-6) of the Inagi reference in order to demonstrate the unexpected improvement in evaporation of the composition of the present invention. However, the unexpected improvement can not proven by the comparison study result found in the 132 declaration because the result is based on the biased study where the selection of the composition used in the study is made subjectively rather than objectively. For instance, applicant choose the composition 1 among the 12 compositions in the table I, wherein the composition 1 contains least alcohol(e.g. 33% of ethanol) content amount and no oleic acid included, whereas composition 11 or 16 has higher content amount of alcohol(e.g. 42 or 44 % of ethanol,

respectively) with/without oleic acid included. Furthermore the compositions 2 and 10 use isopropyl alcohol(30 and 28, respectively) rather than ethanol, where 51.03% of isopropyl alcohol is used in the applicant's composition. It is conventionally known that evaporation rate is based on the amount and/or the type of volatile component included in the composition. Therefore, the critical elements(e.g. ethanol or isopropyl alcohol) used in the study are not same and thus, one would have anticipated different results between Inagi's composition and the composition of the present invention, and further expected better evaporation rate from the composition of the present invention over the Inagi's composition because of the reasons set forth above. Applicant also fails to show unexpected improvement of anesthetic effect wherein the result shown is limited to the differences in evaporation rates between two composition.

Thus, the 132 declaration is not considered to be effective and fails to over come 102 rejection made in previous office action.

Claim Rejections - 35 USC § 112

New matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for applying a topical anesthetic which comprises 60-80% of a volatile solvent. However, the specification as originally filed specifically fails to teach 60-80% whereas it provides a generic description which supports the percentage(40-80% or 40-70%) of the volatile solvent as shown below(page 7, paragraphs 27 and 31):

[00027] ...wherein the volatile solvent is present in the formulation in an amount between 40-80%...

[00031] ... from about 40-70% alcohol; ...

Although the specification as originally filed teaches these generic description of the percentages of the volatile solvent broader than 40-80%, it fails to teach the claimed arbitrary range of 60%-80%.

Thus, the limited generic disclosure and examples fails to convey to one of ordinary skill in the art that the inventor had possession of the later claimed subject matter(i.e. 60-80%), at the time the application was filed because the claimed invention(i.e. 60-80%) does not have written descriptive support in the application disclosure as originally filed within the meaning of 35 USC 112.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4, 6, 8-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Inagi et al(US 6,429,228).

The instant claims are drawn to a method for applying a topical anesthetic to an area of skin, the method comprising the steps of: (a) forming a homogeneous solution by incorporating into a volatile solvent such as isopropyl alcohol(40-80%) an anesthetic such as lidocaine, prilocaine, or a mixture thereof(e.g. 3-40%) in a lipophilic base such as oleic acid(as needed to the complete the balance); (b) applying the homogeneous solution into the area of skin to be treated; and (c) evaporating the volatile solvent from the homogeneous solution.

As mentioned in the previous office action, Inagi et al teach all the critical elements such as a homogeneous mixture of an anesthetic(e.g. lidocaine, prilocaine(2-12%, see column 2, lines 50-65); oleic acid(1-7%, see column 3, lines 15-27); ethanol or isopropyl alcohol(42-44%, see table 1, lines 10-25); and a pharmaceutically acceptable carrier such as sodium carboxymethylcellulose(thickener, 1%), polyvinyl alcohol or sodium caprlate(emulsifier). Furthermore, Inagi et al teach the a process of making the patented composition and a process of using as a skin medicament, columns 4-6. Thus, all the limitations required by the instant claims are taught or inherently possessed by the patented compositions of Inagi reference, see previous office action for the details.

Thus, all the claimed invention is not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mangione et al(US 6485714).

The instant claims are drawn to a method for applying a topical anesthetic to an area of skin, the method comprising the steps of: (a) forming a homogeneous solution by incorporating into a volatile solvent (60-80%) an anesthetic in a lipophilic base such as oleic acid; (b) applying the homogeneous solution into the area of skin to be treated; and (c) evaporating the volatile solvent from the homogeneous solution.

Mangione et al teach a topical composition comprising a local anesthetic such as lidocaine, prilocaine or a eutectic mixture thereof(see claims 8-10), petrolatum(or white petrolatum) as a skin protectant (see column 7, lines 1-4 and claim 8), isoparaffin as a penetration enhancer(see column 6, line 7) and a carrier such as ethanol or isopropyl alcohol(1-80%, preferably 10-60%, see claim 12 and column 4, lines 6-11).

Although Mangione et al did not exemplify a composition containing all these ingredients together, it would have been obvious to one of ordinary skill in the art to make a topical composition comprising all the said ingredients at the time of the invention was made because Mangione suggests that a combination of all these beneficial additives taught in their patent enhances the efficacy of the patented composition, see column 8, lines 10-15 and claim 8.

Thus, it would have been readily apparent to one of ordinary skill in the art to modify the patented composition to include all the beneficial additives taught in the patent(e.g. petrolatum and local anesthetic(5-30%) with a carrier such as isopropyl alcohol(60%)),

with reasonable expectation of success, because the modification could provide maximum therapeutic effectiveness and the techniques/skills to make such modification would be considered well within the skilled level of the ordinary artisan as evidenced by the cited reference, see column 8, lines 17-21. Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. One would have been motivated to make the modification because the inventions of both application and the cited reference are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Thus, the claimed subject matter(i.e. a method for applying a topical anesthetic composition as claimed) is not considered to be patentably distinct over the prior art of the record.

Response to Arguments

7. Applicant's arguments filed 09/07/2003 have been fully considered but they are not persuasive because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references as mentioned above in this office action.

Conclusion

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Primary Patent Examiner
Art unit 1614